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PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

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in its capacity as elected Office

Date of mailing (day/month/year) 11 March 1999 (11.03.99)	Applicant's or agent's file reference PAJ06788W0
International application No. PCT/GB98/01980	Priority date (day/month/year) 04 July 1997 (04.07.97)
International filing date (day/month/year) 06 July 1998 (06.07.98)	
Applicant POTTER, Charles, David, Ogilvy et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
08 January 1999 (08.01.99)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election
- ☒
- was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer</p> <p>C. Carrié</p> <p>Telephone No.: (41-22) 338.83.38</p>
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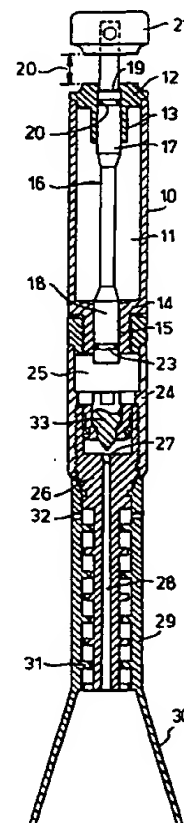
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 5/30, A61K 9/48, A61M 5/315, 5/28		A1	(11) International Publication Number: WO 99/01169
			(43) International Publication Date: 14 January 1999 (14.01.99)
(21) International Application Number: PCT/GB98/01980		(74) Agent: GILL JENNINGS & EVERY; Broadgate House, 7 Eldon Street, London EC2M 7LH (GB).	
(22) International Filing Date: 6 July 1998 (06.07.98)			
(30) Priority Data: 97304909.1 4 July 1997 (04.07.97) EP		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(71) Applicant (for all designated States except US): POWDER-JECT RESEARCH LIMITED [GB/GB]; 4 Robert Robinson Avenue, The Oxford Science Park, Oxford OX4 4GA (GB).			
(72) Inventors; and			
(75) Inventors/Applicants (for US only): POTTER, Charles, David, Ogilvy [GB/GB]; Denham House, Church End, Stardlake OX8 7SG (GB). POTTER, David, S. [GB/GB]; 2 Cliff Road, Cowes, Isle of Wight PO31 8BN (GB). BELL-HOUSE, Brian, John [GB/GB]; The Lodge, North Street, Islip, Oxfordshire OX5 2SQ (GB). GREENFORD, John, Christopher [GB/GB]; 11 Park Crescent, Abingdon, Oxfordshire OX14 1DF (GB). CARTER, Fiona [GB/GB]; 1 Howard Street, Oxford OX4 3AY (GB). WEEKES, Stuart [GB/GB]; 39 Lakefield Road, Littlemore, Oxford OX4 4LZ (GB). SHELDRAKE, Colin [GB/GB]; 253 Greys Road, Henley-on-Thames, Oxford RG9 1QS (GB).		Published With international search report.	

(54) Title: SYRINGE AND CAPSULE THEREFOR

(57) Abstract

A syringe, for use in the delivery of a dose of a therapeutic agent entrained within a pressurized fluid flow, is characterized by an upstream portion (10) which is interfaced with a source of fluid under pressure; a downstream nozzle portion (26); and, interposed between the upstream and downstream portion, an intermediate portion having first and second members which are coupled together to provide a closed pocket (40, 51, 58) for containing the dose; and an actuator mechanism (16) for initiating a flow of the fluid through the syringe. One of the first and second members is moveable relative to the other within the syringe to provide an open configuration in which the pocket is opened to expose the dose for entrainment by the fluid as it flows through the intermediate portion and to and through the nozzle. Also provided is a capsule (33) formed from the first and second members.



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EE	Estonia						

PATENT COOPERATION TREATY

PCT

REC'D 28 OCT 1999

WFO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

18

Applicant's or agent's file reference PAJ06788W0		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB98/01980	International filing date (day/month/year) 06/07/1998	Priority date (day/month/year) 04/07/1997	
International Patent Classification (IPC) or national classification and IPC A61M5/30			
Applicant POWDERJECT RESEARCH LIMITED et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 08/01/1999	Date of completion of this report 26.10.99
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Bichlmayer, K-P Telephone No. +49 89 2399 2977 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB98/01980

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-25 as originally filed

Claims, No.:

1-23 as originally filed

Drawings, sheets:

1/7-7/7 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB98/01980

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-11,15-18
	No:	Claims	1,12-14,19-23
Inventive step (IS)	Yes:	Claims	2-11,15-18
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-23
	No:	Claims	

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application, have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Ad section V:

1. Independent Claim 1

In the present case, all the features of independent Claim 1 are known in combination from the document D1 = WO/A,9 424 263. Using the wording of Claim 1 D1 discloses a capsule (28) adapted for containing a dose of a therapeutic agent to be delivered within a pressurized fluid flow, said capsule comprising a first member (33) and a second member (34), wherein said first and second members are coupled together to provide a closed pocket for containing the dose. As can be taken from the description at page 19, second paragraph, in use said members (33) and (34) are burst by a fluid pressure exerted on the capsule wherein during this burst step at least one of the membrane members (33) or (34) is apparently moved relative to the other when contacted with said pressurized fluid. Thus, the subject-matter of Claim 1 lacks novelty against D1 such that the requirements of Art. 33(2) PCT are not met.

2. Dependent Claims 12 and 13

The features of the dependent Claims 12 and 13 are also known from D1 (see ring (31); membranes (33) and (34) sealably coupled together over ring (31) wherein said capsule is prefilled with the dose of the therapeutic agent; see at page 17, lines 23 to 33). Therefore, said claims do not meet the requirements of Art. 33(2) PCT.

3. Independent Claim 14

Since D1 discloses a syringe comprising all the features defined in Claim 14 (see for example Fig. 1), the subject-matter of Claim 14 does not meet the requirements of Art. 33(2) PCT.

4. Dependent Claims 19 to 23

The features of these dependent claims are also considered to be known

from D1 (see for example at page 19, second paragraph; at page 17, line 25; Fig. 1; stronger Mylar diaphragm (34)). Thus, Claims 19 to 23 lack novelty over D1, contrary to the conditions set out in Art. 33(2) PCT.

5. Dependent Claims 2 to 11, 15 to 18

The dependent Claims 2 to 11 and 15 to 18 in combination with their respective independent claim appear to meet the requirements of Art. 33(2) to (4) PCT.

Ad section VII:

1. The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1 =WO,A,9 424 263; cited by the applicant) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Ad section VIII:

The vague statement in the description on page 25 (spirit of the invention) implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, PCT/GL/3 III, 4.3a).

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PAJ06788W0	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 98/ 01980	International filing date (day/month/year) 06/07/1998	(Earliest) Priority Date (day/month/year) 04/07/1997
Applicant POWDERJECT RESEARCH LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).
2. ☒ Unity of invention is lacking (see Box II).
3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing
 - ☐ filed with the international application.
 - ☐ furnished by the applicant separately from the international application,
 - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
 - ☐ Transcribed by this Authority
4. With regard to the title, ☒ the text is approved as submitted by the applicant
 - ☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,
 - ☐ the text is approved as submitted by the applicant
 - ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is:
 - Figure No. 1 ☐ as suggested by the applicant. ☐ None of the figures.
 - ☒ because the applicant failed to suggest a figure.
 - ☐ because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 98/ 01980

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 98/01980

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

A syringe, for use in the delivery of a dose of a therapeutic agent entrained within a pressurized fluid flow, is characterized by an upstream portion (10) which is interfaced with a source of fluid under pressure; a downstream nozzle portion (26); and, interposed between the upstream and downstream portion, an intermediate portion having first and second members which are coupled together to provide a closed pocket (40,51,58) for containing the dose; and an actuator mechanism (16) for initiating a flow of the fluid through the syringe. One of the first and second members is moveable relative to the other within the syringe to provide an open configuration in which the pocket is opened to expose the dose for entrainment by the fluid as it flows through the intermediate portion and to and through the nozzle. Also provided is a capsule (33) formed from the first and second members.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 98/01980

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M5/30 A61K9/48 A61M5/315 A61M5/28

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 144 551 A (BECTON DICKINSON CO) 19 June 1985 see page 8, line 24 - page 9, line 32 see page 11, line 5-10 see figures 2,4 ---	1,2,8, 13-15, 20,21,23
X A	US 5 125 892 A (DRUDIK ARNIE) 30 June 1992 see column 3, line 40-63 see column 8, line 11-22 see column 9, line 40-45 see figures 1,2,9,20 --- -/--	1,14 10



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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Date of the actual completion of the international search

8 October 1998

Date of mailing of the international search report

21/10/1998

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Authorized officer

Bichlmayer, K-P

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 98/01980

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 12513 A (OXFORD BIOSCIENCES LTD ;BELLHOUSE BRIAN JOHN (GB); DRAYSON PAUL RU) 2 May 1996 see page 1 - page 3 see page 4, line 28 - page 5, line 5; figure 1 ---	1, 14
A	WO 94 24263 A (OXFORD BIOSCIENCES LTD ;BELLHOUSE BRIAN JOHN (GB); SARPHIE DAVID F) 27 October 1994 cited in the application see page 1, line 30 - page 2, line 2 see page 5, line 25-35 see page 11, line 35 - page 13, line 12 see figures 1,5,8 ---	1, 14, 19, 21, 22
A	US 5 614 217 A (CHIPRICH TIMOTHY B ET AL) 25 March 1997 see column 3, line 35-55 see figure 2 ---	1
A	DE 21 18 993 A (CEGLA ULRICH) 23 November 1972 see page 1, paragraph 2 - page 2, paragraph 1; figures 1,2 -----	18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 98/01980

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0144551 A	19-06-1985	AU 2843084 A BR 8402950 A DK 375284 A JP 60072561 A	04-04-1985 11-06-1985 29-03-1985 24-04-1985
US 5125892 A	30-06-1992	CA 2016870 C CA 2016870 A	29-03-1994 15-11-1991
WO 9612513 A	02-05-1996	AU 3703895 A CA 2199417 A EP 0788386 A JP 10507390 T	15-05-1996 02-05-1996 13-08-1997 21-07-1998
WO 9424263 A	27-10-1994	AT 148497 T AU 674742 B AU 6435194 A BG 100047 A BR 9406455 A CA 2159452 A CN 1120852 A CZ 9502608 A DE 69401651 D DE 69401651 T DK 693119 T EP 0693119 A EP 0734737 A ES 2098131 T FI 954788 A GR 3022939 T HU 73516 A JP 8509604 T LV 11833 A LV 11833 B NO 953994 A NZ 263606 A PL 311005 A SG 48696 A SI 693119 T SK 124895 A US 5630796 A	15-02-1997 09-01-1997 08-11-1994 30-04-1996 02-01-1996 27-10-1994 17-04-1996 15-05-1996 13-03-1997 15-05-1997 28-07-1997 24-01-1996 02-10-1996 16-04-1997 06-10-1995 30-06-1997 28-08-1996 15-10-1996 20-08-1997 20-12-1997 06-10-1995 22-08-1997 22-01-1996 18-05-1998 31-10-1997 08-01-1997 20-05-1997

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 98/01980

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9424263	A		ZA 9402442 A	10-04-1995
US 5614217	A	25-03-1997	NONE	
DE 2118993	A	23-11-1972	NONE	